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Original Review Article

Legal Aspects of Tele-health in India

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Abstract

Introduction: This article reviews various legal provisions in India affecting the practice of telehealth either directly or indirectly, on the background of 'Telemedicine Practice Guidelines' (enabling RMPs to provide healthcare using telemedicine), published by the erstwhile Board of Governors in supersession of Medical Council of India (now dissolved), in partnership with NITI Aayog. Attempt has been made to compile and review various legal provisions affecting the practice of tele-health either directly or indirectly. **Material and Methods:** This is a review article. List of articles reviewed is provided at the end of the article. **Results and Conclusion:** A welcome step is taken by the erstwhile Board of Governors by publishing the 'Telemedicine Practice Guidelines'. However the guidelines are limited to 'telemedicine' and further efforts are needed for guidance of 'telehealth' practices in India.

1. Introduction

Before National Medical Commission came into force wef 25/09/2020, the erstwhile Board of Governors in supersession of Medical Council of India (now dissolved), in partnership with NITI Aayog have prepared 'Telemedicine Practice Guidelines' enabling RMPs to provide healthcare using telemedicine. These were published on 25/03/2020 and constitute Appendix 5 of the IMC (Professional Conduct, Etiquette and Ethics) Regulation, 2002.¹ It is the first such document in the field of telemedicine made available by a statutory body to Indian allopathic doctors. These guidelines were intended to be used in conjunction with other national clinical standards, protocols, policies, and procedures. These guidelines were intended only for practitioners of modern medicine, as it has defined 'A Registered Medical

Practitioner [RMP], as a person who is enrolled in the State Medical Register or the Indian Medical Register under the Indian Medical Council Act 1956.' [IMC Act, 1956].² Its scope is limited to tele-consultations within Indian jurisdiction.

Though these guidelines define both Telemedicine as well as Telehealth, however the entire document deals only with telemedicine. Telehealth, being a broader term has been specifically excluded from the scope of these guidelines. As a result, it does not address the issues of specifications of hardware or software, infrastructure building and maintenance, data management systems involved, standards and interoperability, use of digital technology to conduct surgical or invasive procedures remotely, use of telehealth in research, CMEs etc.

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This article addresses some legal aspects of telehealth (which includes telemedicine), which the doctors should be aware of.

Following are some of the examples of Telehealth.

- Telemedicine
- Robot- Assisted Surgery
- Self-monitoring Health-care devices
- Electronic Health Records
- Health Service Aggregation
- M-Health
- Big data in health care
- Targeted Advertisement
- e-Pharmacies
- E-Learning in health sector

In India telemedicine programs are actively supported by Dept. of Information Technology, Indian Space Research Organization (GRAMSAT), State governments, NEC Telemedicine program for North-Eastern states, some other private organizations and hospitals.

Currently, there are four primary methods of telehealth, which include live video, store-and-forward, remote-patient monitoring and mobile health.

2. Laws Governing Tele-health services

The laws that broadly cover Tele-Health services include:

- The Information Technology Act, 2000 (“IT Act”),³
- The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“Data Protection Rules”) and⁴
- The Information Technology (Intermediaries Guidelines) Rules, 2011⁵
- Indian Medical Council Act, 1956,²
- The Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulation 2002)¹
- Drugs & Cosmetics Act, 1940 and Rules 1945,⁶
- Clinical Establishment (Registration and Regulation) Act, 2010,⁷
- Unsolicited Commercial Communications Regulations, 2007 (“UCC Regulations”) and Telecom Commercial Communication Customer Preference Regulations, 2010 (“TCCP Regulations”)⁸
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs and Magic

Remedies (Objectionable Advertisements) Rules, 1955 (“DMRA”)⁹

- Pharmacy Practice Regulations, 2015¹⁰

Information Technology Rules 2011;⁴ categorize ‘medical records and history’, as “**Sensitive Personal Data or Information (SPDI)**”. Thus

- Before a doctor or an institution does anything with patients’ data, they are required by law to obtain the recipient’s consent in writing. The patient must be informed about the fact that the data is being collected, what it will be used for and whether it would be transferred to any third parties, along with the contact details of the agency collecting the information.
- Body corporate (means any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities) should have privacy policy in place and published on its website.
- This consent is usually obtained by having the patient accept the terms of the body corporate’s privacy policy, which is also required to have such information, in addition to the security practices the body corporate has adopted to keep the information safe.
- In cases where the SPDI is being transferred, the body corporate transferring the SPDI must ensure that the receiver of the SPDI has adequate security practices in place.
- The Data Protection Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure.
- This requirement is fulfilled if the body corporate conforms to the international standard IS/ISO/IEC 27001 on “Information Technology – Security Techniques – Information Security Management System – Requirements” or similar standards that are approved and notified by the Central Government.
- Other provisions include Appointment of ‘Grievance Officer’ and allowing users to opt-out or modify their SDPI if required.

In 2013, Ministry of Communication & Information Technology (MOCIT) clarified that Body corporate that were collecting, storing, processing or transferring information out of a contractual obligation were not required to observe some of the

requirements of the Data Protection Rules such as obtaining consent from the owner of the SPDI for collecting or disclosing the SPDI. The other requirements, however, must still be observed.

Sec 2(w) of the Information Technology act 2000³ defines an “intermediary,” with respect to any particular electronic records. It means any person who on behalf of another person receives, stores or transmits that record or provides any service with respect to that record and includes telecom service providers, network service providers, internet service providers, web-hosting service providers, search engines, online payment sites, online-auction sites, online-market places and cyber cafes. MOCIT has framed guidelines for these intermediaries, which include guidelines for due diligence to be observed while discharging its duties. Intermediaries have set ups that merely facilitate the interaction between the patient and the service provider and are not directly involved in the provision of the services.

As per the guidelines issued by **Department of Telecommunications (DoT)** the “**Other Service Providers (OSP)**” has been defined. On 21 October 2019, the Telecom Regulatory Authority of India (TRAI) has provided its recommendations reviewing the terms and conditions for registration of ‘OSPs’. It defines OSP as a Company or Limited Liability Partnership (LLP) providing services like Business Process Outsourcing (BPO), Billing Service Centre, e-Publishing Centre, Financial Service, Knowledge Process Outsourcing (KPO), Medical Transcript Service, Network Operating Centre, Tele-Medicine, Tele Education, Tele-Trading, Vehicle Tracking Centre or Other similar services on outsourced basis i.e. on behalf of another entity using Telecom Resources provided by authorized Telecom Service Providers. These OSPs are required to be registered as an ‘Other Service Provider’ (“**OSP**”) with the Department of Telecommunications.

The Drugs and Cosmetics Act, 1940 (“D&C Act”) and Drugs and Cosmetics Rules, 1945 (“D&C Rules”)⁶

- The D&C Act states that no person can sell any drug without a license issued by the licensing authority.
- The D&C Rules also state that prescription drugs (Schedule H, H1 and X) can only be dispensed on the production of a prescription which is in accordance with the provisions of the rules.

On 28th August 2018, Ministry of Health & Family Welfare published a Notification in the Gazette of India containing **draft of Drugs and Cosmetics Rules (to be amended) for e-pharmacy** and invited objections and suggestions from the public.

One issue that is peculiar to India is, in India there is no separate category of medicines as ‘Non-Prescription drugs’ or ‘Over the Counter (OTC)’ drugs. As a result, even the Schedule K drugs (tincture iodine, eucalyptus oil, paracetamol, cough and cold medicines) are also not specifically categorized as ‘OTC’ drugs. Thus, medicines are sold as OTC, by exclusion; i.e., those drugs which are not ‘prescription drugs’ are understood to be OTCs. With advent of e-pharmacy and Telehealth, separately identifying and categorizing OTCs, is the need of hour in India.

As per rules, irrespective of the schedule in which a medicine may fall, prescription of a medicine can be made only by a registered medical professional. A “**prescription**” has been defined under Section 65(10) of the Drugs & Cosmetic Rules, 1945, so as to have the following components-

- be in writing and be signed by the person giving it with his usual signature and be dated by him;
- specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use;
- Indicate the total amount of the medicine to be supplied and the dose to be taken.

Pharmacy Practice Regulations, 2015,¹⁰ defines: “**Prescription**” means a written or electronic direction from a Registered Medical Practitioner or other properly licensed practitioners such as Dentist, Veterinarian, etc. to a Pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to a patient.

For all medical treatments through telemedicine or web-interface format, it is important to ensure that the prescriptions must satisfy the above requirements of being in writing and signed by a registered medical practitioner, without which the prescription will be invalid in the eyes of the law.

- Digital signatures are legally recognized under Section 5 of the IT Act, 2000, which states: "where any law provides that information or any other matter shall be authenticated by affixing the signature or any document shall be signed or

bear the signature of any person then; notwithstanding anything contained in such law, such requirement shall be deemed to have been satisfied, if such information or matter is authenticated by means of digital signature affixed in such manner as may be prescribed by the Central Government."

- Digital Signatures are a type of Electronic Signature that uses a certificate-based Digital ID, obtained either from a cloud-based trust service provider, or from the signer's local system.

The Indian Medical Council Act, 1956 ("MCI Act")², The National eMedical Commission Act, 2019¹¹ ("NMC Act") and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 ("MCI Code")¹: These provide for following:

- Only those persons who have a recognized degree in medicine and are registered with one of state medical councils have the right to practice medicine in India.
- Professional and ethical standards of interaction of doctors with patients.
- Efforts are to be made to computerize medical records so that they can be retrieved quickly.
- Doctors are bound by the MCI Code and are required to submit a declaration to that effect.

These principles will have to be reviewed on the background of practice of tele-health. Also, the machinery and mechanism for disciplining the defaulters will have to be upgraded, to keep pace with the advancing technology.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 ("DMRA"):⁹ With rising percolation of tele-health services in India, there are chances of non-compliance to the provisions of these acts.

Unsolicited Commercial Communications Regulations, 2007 ("UCC Regulations") and Telecom Commercial Communication Customer Preference Regulations, 2010 ("TCCP Regulations"):⁸ Sending unsolicited commercial communications over voice or SMS are prohibited under the TCCP Regulations and UCC Regulations. In order to increase their clientele, companies providing tele-health platform to doctors might be seen flouting these provisions.

The Clinical Establishments (Registration and Regulation) Act, 2010 ("Clinical Establishments Act")⁷

Though not yet implemented in the state of Maharashtra, however, it will be pertinent to strictly follow the provisions of this act in concerned states. Also, important amendments are expected in this act in view of the practice of tele-health.

Department of Information Technology (DIT), Ministry of Communications and Information Technology (MCIT), in the year 2003 has prepared a **Report of the Technical Working Group on Telemedicine standardization.**¹² It has

recommended guidelines and standards for practice of Telemedicine in India. It was submitted to a committee for standardization of digital information to facilitate implementation of telemedicine systems using information technology enabled services. This document delineates:

- Necessary information on standards required for hardware, software and clinical devices including the security aspects and finally the Telemedicine Process guidelines.
- A framework for defining the scope of standards addressing the requirement of Infrastructure for Hardware, Software, Minimum Data Sets (MDS) and Unique Identifiers.
- Details of specifications for Infrastructure required in terms of Telemedicine Hardware like the Computer systems, the clinical devices like ECG, X-Ray digitizer, Glucometer, etc and the specifications for video conferencing units.
- The communication hardware details like, LAN/PSTN/ISDN/VSAT including GSM & CDMA mobile have been indicated.
- System requirement for different classes & levels of Telemedicine centers like Primary, Secondary and Tertiary.
- Software standards in terms of requirement of operating system, telemedicine software, user interface, Patient Information Records, storage & transmission formats.
- Digital Imaging & Communication in Medicine (DICOM), the Minimum Data Sets (MDS) & Identifiers.
- The Security aspects for Telemedicine, which is one of the important factors for Telemedicine Practice with respect to the security mechanisms including signature schemes.

- Patient's critical confidentiality records, Telemedicine Centre guidelines and the protocols for each of these methodologies including the consent form to be used for ensuring quality consultation & treatment.

Thus, this document, in fact, truly complements the 'Telemedicine Practice Guidelines' by erstwhile BOG. It covers the technical aspect of telemedicine, which the 'Telemedicine Practice Guidelines' has specifically excluded. It serves as a ready reckoner for judicious adaptation of the Information & Communication Technology for the practice of Telemedicine at any level of Health care delivery in India. However, this document, which was prepared 17 years ago, needs a serious updating, in view of the tremendous progress in the telecommunication as well as health sectors over these years. [We are not aware of whether it has been updated or not. We failed in our attempts to search for an updated edition].

IAMAI

- According to Internet and Mobile Association of India (IAMAI), in the absence of any legal provision that prohibits online medical consultations or prescribes the manner of communication between medical practitioners and patients, **there is no illegality in providing medical consultations online in India subject however, to compliance with all other laws that may be applicable, including the MCI Act, The Code of Ethics and other laws that may be applicable to activities involved in the process, such as the Drugs and Cosmetics Act, 1940 that deals with the issuance of prescriptions.**

In the High Court of Judicature at Bombay, Criminal Appellate Jurisdiction, Criminal Anticipatory Bail Application No. 513 of 2018 [Deepa Sanjeev Pawaskar and Sanjeev Pawaskar versus the State of Maharashtra]¹³

- Registered ANC case. Elective LSCS. Discharged in absence of doctors. Post-op care not explained. Next day of discharge, patient started vomiting. Relatives called the doctor on phone. Doctor told them to call from medical shop. Doctor gave instructions chemist on phone. Chemist gave tablets to patient. Patient consumed tablets. Vomiting continued, fever started. Patient went to hospital at 8:30 pm. Doctors were not available. They were out of

station on a pre-scheduled visit. However, on phone they advised to admit the patient. Accordingly, patient was admitted. Patient was being treated by nurses as per telephonic instructions from doctor. Patient's condition deteriorated. Some other doctors visited the patient (other than Dr. Pawaskars). Condition further deteriorated. Patient shifted to other hospital, however expired on admission. Autopsy revealed Pulmonary Embolism.

- The main issue before the court was whether the act of doctor Pawaskars would fall under IPC section 304A (Causing death by Rash and Negligent Act) or under IPC Section 304 (Culpable Homicide not amounting to Murder)?
- In its order, the Court does not say medicines ought not to have been prescribed at all over the telephone. The issue under consideration by the Court was "Prescription without diagnosis and hence resulting in death of the patient amounts to criminal negligence on the part of the doctors."
- This can be comprehended to mean that prescription without diagnosis, resulting in fatal consequences, would amount to culpable negligence, which the Bombay High Court affirmatively decided. The court also mentioned "The medicines were administered on telephonic instructions without even inquiring about the symptoms or nature of the pain suffered by the patient." Anticipatory bail was denied.
- However, the Hon'ble Supreme court was of different view, that, in an established patient-doctor relationship, telephonic and telemedicine consultation do not amount to negligence. It granted the doctors relief from arrest under Sec 304 IPC.

The Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulations, 2002 (the "Code of Ethics")¹ laid down by the MCI, prescribes standards of professional conduct, etiquette and ethics for registered medical practitioners. There is nothing in this Code of Ethics that prohibits the online practice of medicine, provided due diligence is exhibited by the doctor and there is no other law in India that prohibits online medical consultations or prescribes the manner of communication between a medical practitioner and a patient.

Inter-state e-health services

- In terms of the MCI Act, once a doctor/medical practitioner is qualified and registered in any one of the state medical registers maintained by the respective states, a copy of his/her registration certificate is forwarded to the Medical Council of India for enrollment of his/her name in the Indian medical register (national database). In terms of Section 27 of the MCI Act, any person whose name is enrolled in the Indian medical register can practice as a medical practitioner in any state of India according to his qualifications. Hence, inter-state practice of Telemedicine by medical practitioners is permissible.

Online health service companies/ Apps etc

- Advertisement in media by these companies inviting doctors to join their panel of online consultants
- MCI Code of Ethics Regulations: Soliciting of patients directly or indirectly, by a physician, by a group of physicians or by institutions or organizations is unethical
- KMC (June 2018): Threatens to initiate action against doctors who take up online consultations

IMA

- In situations where physical examination is not required — like adjusting insulin according to blood sugar levels in a regular patient, analgesics for acute exacerbation of chronic pain under regular treatment, etc. — telephonic consultation will not amount to negligence.
- Also, in situations of managing emergencies till the doctor arrives, telephonic consultation can be undertaken in a judicious manner.
- In this type of consultation, there is an element of contributory negligence on the part of the patient or relatives if they by themselves opt for telephonic consultation,

Curbside consultation

In a curbside consultation, the treating physician seeks informal information or advice about patient care from another doctor colleague to assist in the management of a particular, real patient. It can happen in a hallway, elevator, sidewalk, and canteen or by telephone. Often the colleague has a particular expertise which can come handy and prove to be useful for the patient.

To obtain curbside consults the seeker presents the case or asks direct questions. The colleague consultant does not see the patient or review the chart, but instead obtain details by asking further questions. The colleague is not paid for the consultation.

Here, doctor-patient relationship is not established between the colleague doctor and the patient. The physician giving the opinion provides an informal service to the physician seeking consultation rather than to the patient. In fact, a patient may not even know if or when her or his physician obtained a curbside consult. The physician seeking the curbside consult remains free to exercise her or his own professional judgment; in accepting, rejecting, or otherwise relying on the consultant colleague's advice.

Telephonic Consultations

- To be avoided as a routine
- May be given if:
 - In acute emergency
 - If there is an established Doctor-Patient relationship
 - Doctor is aware of the diagnosis
 - May be given to another doctor who is with the patient
- It should be limited to conveying of results of tests/ to manage the acute phase till the patient can reach a nearby doctor
- Telephonic consultations should be documented
- Doctors should also be careful about any recordings being made by the patient
- Doctors should mind the tone and contents of the conversation
- Confidentiality and privacy of the consultation should be maintained.
- No data/ information should be shared without prior consent of the patient
- Doctors should be fully cognizant of the attendant risks, both medical and medicolegal.

3. Legal Liabilities**Suits before civil court**

- For breach of contractual obligations between e-health service provider and the patient/ user
 - Payment of liquidated damages (decided at the time of contract)

- Un-liquidated damages (on court decision)
- For commission of a tort such as negligence on the part of the service provider or its employees
- Amount claimed as consequential damages

Vicarious Liability

- E-Health Employer- Employee relation
- Employer vicariously liable for acts and omissions of the employee arising in course of his/her employment
- No vicarious liability in employer-independent contractor relationship, where the service provider does not have much control or supervision over the acts of the independent contractor.

Liability under Consumer Protection Act

- Deficiency in Service
- Unfair trade practice
- Defective products

Disciplinary Action by MCI

- SMC
- NMC: Ethical Committee (EMRB)

Criminal Liability

- "GROSS" Negligence
- Expert Medical Committee
- IPC 304A, 336, 337, 338
- No vicarious liability of employer

Further regulations required

- Online procedure of obtaining specific consent for telemedicine services
- Archival and retrieval of patient records
- Implementation of Quality oversight mechanism
- Cross-state licensing
- Insurance coverage for tele-medicine services
- Patient privacy and confidentiality
- More clarity on online prescriptions
- m-Health: USFDA divided mobile applications into three categories:
 - mobile applications that are considered medical devices and subject to USFDA regulations,
 - mobile applications that may be considered medical devices, but which the FDA does not currently intend to regulate, and
 - mobile applications that could be used in a health care environment, but are not considered medical devices

- Standardizing the content to be included in health records,
- Placing legal obligations on doctors to update health records,
- Safeguards for accessing health data and the interoperability of health records.
- Ensuring quality and efficiency as well as supervision and oversight in the performance of such services
- Disclaimers must be put in place that informs the user of the accuracy of the information provided and the possibility of errors, mechanical or otherwise.

5. National Health Stack: NITI Aayog (National institution for Transforming India)

- While the National Health Analytics Framework will initially focus on Health Insurance, it will provide for "horizontal expansibility"—enabling the potential to cover, at a later point in time, important areas including (and not limited to) disease surveillance, predicting epidemics, classifying and clustering population segments for proactive care, nutrition, health schemes, and national health infrastructure such as telemedicine, teleradiology, and the enhancement of process controls.
- The National Health Stack is designed to provide the foundational components that will be required across Ayushman Bharat and other health programs in India. The Health Stack is a nationally shared digital infrastructure usable by both Centre and State across public and private sectors. The Stack is designed to bring a holistic view across multiple health verticals and enable rapid creation of diverse solutions in health. National Health Stack will provide necessary regulations for the telemedicine sector too,"

Attempt has been made to compile and review various legal provisions affecting the practice of tele-health either directly or indirectly. The erstwhile BOG has provided us with the 'Telemedicine Practice Guidelines'. We look forward to NMC to develop a comprehensive and practical 'National Tele-Health Policy' considering its extended scope across various sections and sectors. It will enable the stakeholders to effectively provide and obtain the extended benefits of tele-health in India.

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